



SODIUM HYDROXIDE SOLUTION



BIO PHARMA GRADE FOR BIO SPECTRA PRODUCT LINE REGULATORY PACKET

Signature/Date:



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1. SODIUM HYDROXIDE SOLUTION BIO PHARMA GRADE FOR BIOSPECTRA PRODUCT LINE:

1.1. General Product Information:

- 1.1.1. Product Name:
 - 1.1.1.1. Sodium Hydroxide Solution
- 1.1.2. Product Code:
 - 1.1.2.1. Historic Code: NH4122, NH4123, NH4124, NH4150, NH4151, NH4152, NH4153, NH4154
 - 1.1.2.2. Current Code: NAHY-4122, NAHY-4123, NAHY-4124, NAHY-4150, NAHY-4151, NAHY-4152, NAHY-4153, NAHY-4154
- 1.1.3. Scope:
 - 1.1.3.1. This regulatory packet will provide the quality and regulatory information regarding the manufacturing, testing, packaging, storage, release, shipping, and handling of Bio Pharma Grade Sodium Hydroxide Solution manufactured by and at the BioSpectra Bangor, PA facility.
- 1.1.4. Molecular Formula:
 - 1.1.4.1. NaOH
- 1.1.5. Molecular Weight:
 - 1.1.5.1. 40.00 g/mol

1.2. Manufacturing, Packaging, Release Site and Supplier Information:

- 1.2.1. General Information:
 - 1.2.1.1. BioSpectra manufactures Sodium Hydroxide Solution in its Bangor, PA facility. Sodium Hydroxide Solution is manufactured, packaged, stored, tested and released at BioSpectra's Bangor, PA facility.
- 1.2.2. Manufacturing:
 - 1.2.2.1. The manufacturing of Sodium Hydroxide Solution is performed at BioSpectra's Bangor, PA facility and is conducted in a dedicated processing area using only dedicated equipment. Equipment used in the manufacturing of Sodium Hydroxide Solution is cleaned in accordance with the batch record.
- 1.2.3. Packaging:
 - 1.2.3.1. The packaging of Sodium Hydroxide Solution occurs in the following BioSpectra site: BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
- 1.2.4. Testing for Release:
 - 1.2.4.1. Testing and release of Sodium Hydroxide Solution is performed at the BioSpectra Bangor, PA Facility: 100 Majestic Way, Bangor, PA 18013
- 1.2.5. GMP Compliance Statement:
 - 1.2.5.1. Bio Pharma Grade Sodium Hydroxide Solution is suitable for use as a process chemical. It is manufactured in accordance with the IPEC-PQG Joint Good Manufacturing Practice Guide. This grade of Sodium Hydroxide Solution is not suitable to be used as an Active Pharmaceutical Ingredient, Drug, Drug Product or Household Item.

**1.3. Physico-Chemical Information:**

1.3.1. CAS Number:

1.3.1.1. CAS #: 1310-73-2

1.3.2. Origin:

1.3.2.1. The origin of Sodium Hydroxide Solution is through chemical manufacturing using approved raw materials, which are further purified in accordance with the validated manufacturing process. Raw materials of synthetic and mineral origin are used in the synthesis and purification of Sodium Hydroxide Solution.

1.3.3. Synonyms:

1.3.3.1. Caustic Soda

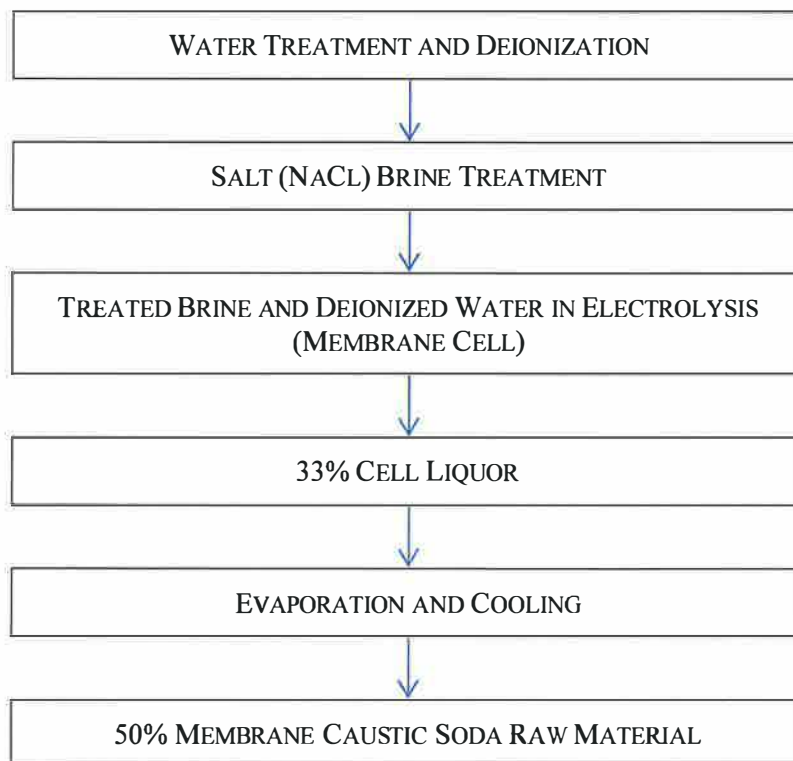
1.3.3.2. Lye

1.3.4. Morphological Form:

1.3.4.1. Clear/Colorless Liquid

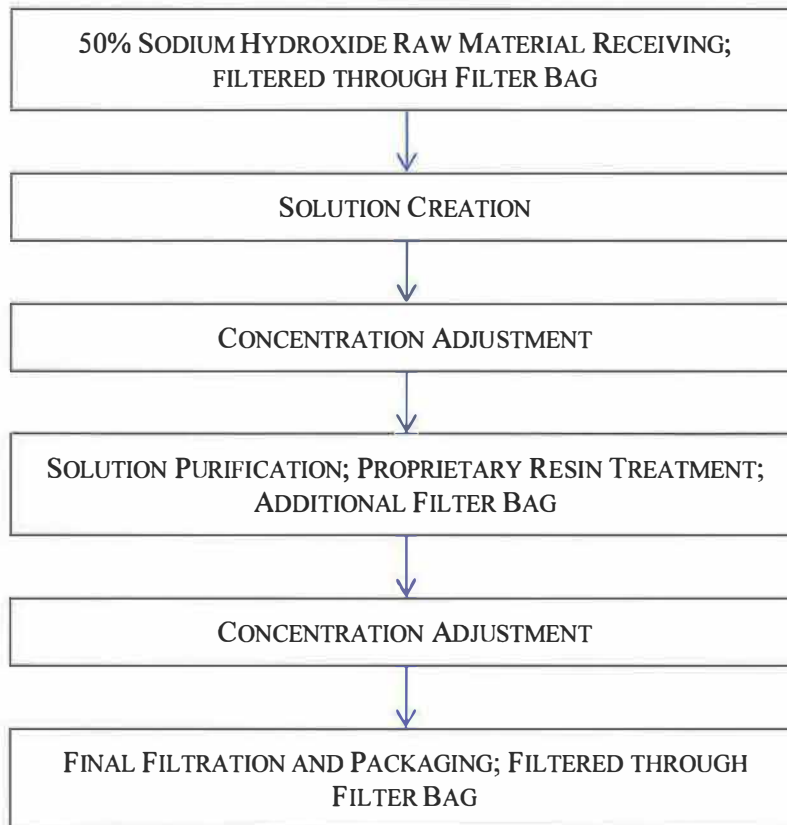
1.3.5. Manufacturing Process:

1.3.5.1. The manufacturing process for Sodium Hydroxide Solution, Bio Pharma Grade is performed by the following:

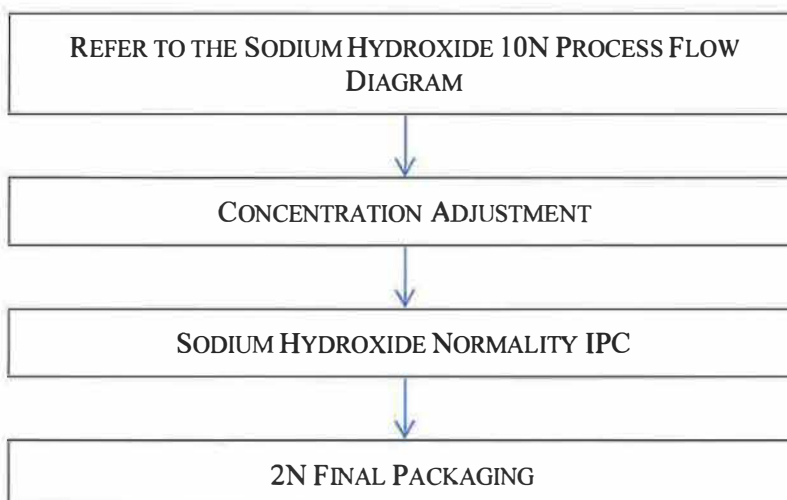
Approved Supplier Raw Material Synthesis



BioSpectra 10N Chemical Manufacturing Process

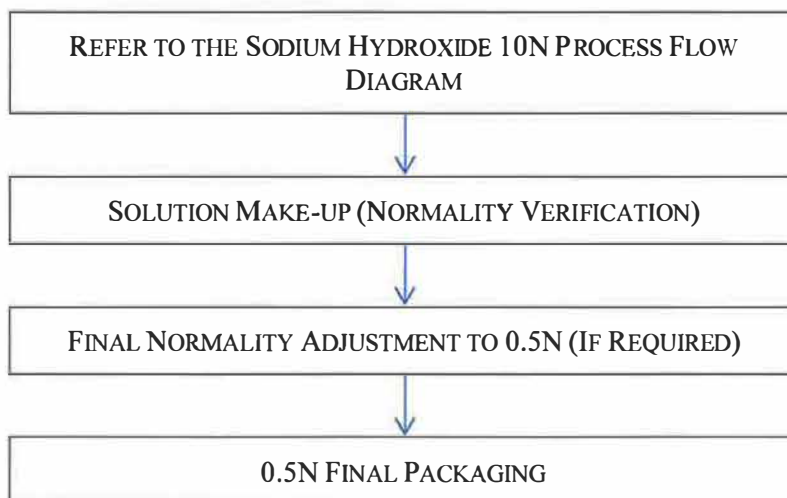


BioSpectra 2N Chemical Manufacturing Process





BioSpectra 0.5N Chemical Manufacturing Process



1.3.6. Specifications:

1.3.6.1. Available upon request.

1.4. Regulatory Information:

1.4.1. Compendial Compliance:

1.4.1.1. Not Applicable

1.4.2. Master File:

1.4.2.1. Drug Master File (DMF) is currently not available for this product.

1.4.2.2. EDQM Certificate of Suitability is currently not available for this product.

1.4.3. REACH:

1.4.3.1. Refer to the Sodium Hydroxide Solution Safety Data Sheet for the REACH Number or contact your Commercial Team Representative for further information.

1.4.4. BSE/TSE Statement:

1.4.4.1. Sodium Hydroxide Solution, Bio Pharma Grade is a synthetic, inorganic chemical and has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that BSE/TSE is not a concern based on this evaluation. Sodium Hydroxide Solution, Bio Pharma Grade and its raw materials are not of animal origin.

1.4.5. Allergens Statement:

1.4.5.1. Sodium Hydroxide Solution, Bio Pharma Grade manufactured by BioSpectra and its raw materials are not manufactured with or using any of the following allergenic substances: Cereals containing gluten (i.e., wheat, rye, barley, oats, spelt, kamut or their hybridized strains) and products thereof, Crustaceans and products thereof, Eggs and products thereof, Fish and products thereof, Peanuts and products thereof, Soybeans and products thereof, Milk and products thereof (including lactose), Celery and products thereof, Mustard and products thereof, Sesame seeds and products thereof, Lupin and products thereof, Molluscs and products thereof, Sulphur dioxide and sulfites at >10 mg/kg as SO₂, Nuts, i.e.,



Almonds (*Amygdalus communis* L.), Hazelnuts (*Corylus avellana*), Walnuts (*Juglans regia*), Cashews (*Anacardium occidentale*), Pecan nuts (*Carya illinoensis* (Wangenh.) K. Koch), Brazil nuts (*Bertholletia excelsa*), Pistachio nuts (*Pistacia vera*), Macadamia or Queensland nuts (*Macadamia ternifolia*) and products thereof, Beef, Chicken, Pork, Azo Dyes, Benzoic Acid, Tartrazine, Vanillin, Cocoa, Cinnamon, Coriander, Yeast, Glutamate, Legumes, Corn, Animal and animal by-products, Monosodium glutamate (MSG), and Coconut. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.

- 1.4.6. Genetically Modified Organisms (GMO) Statement:
- 1.4.6.1. Sodium Hydroxide Solution, Bio Pharma Grade has been evaluated for the source of the raw materials used in its production through the Supplier Qualification Program. BioSpectra can state that genetic modification is not a concern based on this evaluation.
- 1.4.7. Residual Solvents Statement:
- 1.4.7.1. BioSpectra does not intentionally add or use any solvents in the manufacturing process of Sodium Hydroxide Solution, Bio Pharma Grade. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that there are no solvents added or used in the raw material manufacturing process. BioSpectra does not specifically analyze Sodium Hydroxide Solution or its raw materials for residual solvents. Based on the manufacturing process and the controlled handling and storage of this product, the Sodium Hydroxide Solution manufactured by BioSpectra is expected to comply with the requirements and specifications listed in the current ICH Q3C Residual Solvents Guideline and USP <467> Residual Solvents.
- 1.4.8. Metal Catalyst and Metal Reagent Residues Statement:
- 1.4.8.1. Sodium Hydroxide Solution manufactured by BioSpectra, and its raw materials, are manufactured without the use of metal catalysts and metal reagents. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program.
- 1.4.9. Pallet Statement:
- 1.4.9.1. BioSpectra can state that all wooden pallets used in the packaging of Sodium Hydroxide Solution manufactured at BioSpectra are ISPM 15 compliant.
- 1.4.10. Elemental Impurities Statement:
- 1.4.10.1. BioSpectra's Sodium Hydroxide Solution, Bio Pharma Grade material has been profiled for elemental impurities via ICP utilizing USP <232> and <233> in accordance with ICH Q3D. The results are reported in the associated Elemental Impurity Profile and are available upon request.
- 1.4.11. Melamine Statement:
- 1.4.11.1. BioSpectra does not intentionally add or use melamine in the BioSpectra manufacturing process of Sodium Hydroxide Solution. BioSpectra has evaluated the raw material supply through the Supplier Qualification Program and can state that the raw materials are not expected to contain melamine based on this evaluation. BioSpectra analyzes Sodium Hydroxide Solution annually for Melamine with a specification of 2.5 mg/kg max.

**1.5. Miscellaneous Product Information:**

1.5.1. Description of Batch:

1.5.1.1. The Sodium Hydroxide Solution process is a batch process where expected batch yields are established during validation in accordance with the Manufacturing Process Validation Master Plan. Individual batch yield is additionally determined for each manufactured batch and documented in the respective batch record.

1.5.2. Lot/batch numbering system:

1.5.2.1. The lot numbering system at BioSpectra employs the following format: 4 alphanumeric digits followed by a hyphen, 4 numerical digits followed by a hyphen, and finally 5 numerical digits. A sample lot number would appear as NAHY-0123-00001.

1.5.2.1.1. The first four digits are alpha digits which indicate the material manufactured, where NAHY represents Sodium Hydroxide Solution. The fifth and sixth digits are numeric digits which indicate the site of final packaging, where 01 represents the Bangor, PA facility. The seventh and eighth digits are numeric digits which indicate the year the batch record was issued, where 23 represents 2023. The final five digits are numeric digits which indicate the sequential batch number, where 00001 represents the first Sodium Hydroxide batch of 2023 that is automatically generated by the ERP system. The sequential batch number automatically resets on the first of the new calendar year.

1.5.3. Expiration date and/or recommended re-evaluation interval:

1.5.3.1. The current recommended Retest or Expiration Date for Sodium Hydroxide Solution, Bio Pharma Grade is available in the BioSpectra Product Retest and Expiration Date List, DCN: BSI-LST-0239, and is based on current available stability data in accordance with BioSpectra's Stability Testing Program. Additionally, the recommended Retest or Expiration Date will be available on the Product Specific Certificate of Analysis, as applicable.

1.5.4. Storage and shipping conditions:

1.5.4.1. Refer to the Sodium Hydroxide Solution SDS for the Storage Conditions applicable to the specific concentration purchased.

1.5.5. Packaging:

1.5.5.1. Packaging information is available through the following:
<https://Biospectra.us/packaging>

1.6. Contact Information:

1.6.1. <https://www.biospectra.us/about-us/commercial-marketing-team>